Kiwa Cermet Italia

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2023/03/29

Stimata/Esteemed

MEDICA S.p.A
Via degli Artigiani ,7
41036 Medolla (MO)
Italia
Letter Reference: MDR 00048

Subject: Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

To whom it may concern,

This letter confirms that, Kiwa Cermet Italia, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0476 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

MEDICA S.p.A
Via degli Artigiani ,7
41036 Medolla (MO)
Italia

SRN Number: IT-MF-000025691

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 20 March 2023, this letter also confirms that the manufacturer submitted the MDR application and signed the written agreement by the date of MDD certificate expiry (ref. MED 23010A rev 29 expiry date 17/03/2023)

Yours faithfully,

Kiwa Cermet Italia

Spett.le

MEDICA S.p.A
Via degli Artigiani ,7
41036 Medolla (MO)
Italia
Riferimento lettera: MDR 00048

Oggetto: Conferma del ricevimento di una domanda formale e conclusione di un accordo scritto nell'ambito del Regolamento UE 2023/607 che modifica i Regolamenti (UE) 2017/745 e (UE) 2017/746 per quanto riguarda le disposizioni transitorie per taluni dispositivi medici e dispositivi medico- diagnostici in vitro.

A chi di interesse,

la presente lettera conferma che Kiwa Cermet Italia, Organismo Notificato (NB) designato ai sensi del Regolamento (UE) 2017/745 e identificato con il numero 0476 su NANDO, ha ricevuto domanda formale conformemente all'Allegato VII, punto 4.3, primo comma ed ha firmato un accordo scritto conformemente all'Allegato VII, punto 4.3, secondo comma del suddetto Regolamento con il seguente Fabbricante:

MEDICA S.p.A
Via degli Artigiani ,7
41036 Medolla (MO)
Italia

SRN: IT-MF-000025691

I dispositivi oggetto della domanda formale e dell'accordo scritto di cui sopra sono indicati alla fine della presente lettera.

In caso di dispositivi i cui certificati rilasciati ai sensi della Direttiva 93/42/CEE siano scaduti prima della pubblicazione del Regolamento UE 2023/607 del 20 Marzo 2023, la presente lettera conferma inoltre che il Fabbricante ha presentato domanda formale e firmato un accordo scritto entro la data di scadenza del certificato MDD (rif. doc.: MED 23010A rev 29 data di scadenza 17/03/2023).

In fede,

Kiwa Cermet Italia
Medical Devices Division
Division Manager
Alessio Faccetti

Devices covered by this letter/ Dispositivi oggetto della presente lettera:

Device name / Basic UDI-DI (under MDR application)	**Device classification under MDR (as proposed by the manufacturer and verified at the pre-application stage)**
SETS AND ACCESSORIES FOR ISOLATED PERFUSION OF A LIMB BASIC UDI-DI: 803377232BLD-ILP8Q	Class IIa
SETS AND ACCESSORIES FOR EXTRACORPOREAL BLOOD AND BLOOD PARTS MANAGEMENT BASIC UDI-DI: 803377232BLD-LBF7M	Class IIa
SETS AND ACCESSORIES FOR HEMODIALYSIS BASIC UDI-DI: 803377232BLD-HML8E	Class IIa
SETS AND ACCESSORIES FOR REMOVAL OF EXCESS CO2 BASIC UDI-DI: 803377232BLD-CO269	Class IIa
Sets for the treatment of Hypothermic Oxygenated Organ Perfusion BASIC UDI-DI: 803377232INF-ORPFF	Class IIa
Sets for the chemohyperthermic locoregional oncological treatments BASIC UDI-DI: 803377232INF-HTPEJ	Class IIa
Sets for the hemodialysis treatment BASIC UDI-DI: 803377232INF-DRLDG	Class IIa
Sets for hemofiltration BASIC UDI-DI: 803377232HMF-SETE6	Class IIb
Hemofiltration devices BASIC UDI-DI: 803377232HMFJ6	Class IIb
Hemoconcentration devices BASIC UDI-DI: 803377232HMCHY	Class IIb
Sets for hemoconcentration	Class IIb

BASIC UDI-DI: 803377232HMC-SETD5	
Catheters for oro-esophageal manometry BASIC UDI-DI: 803377232CAT-G0103G6	Class IIa
Catheters for gastro-intestinal manometry BASIC UDI-DI: 803377232CAT-G0206GH	Class IIa
Catheters for cyst- and urethronometry without balloon BASIC UDI-DI: 803377232CAT-U0501MG	Class IIa
Catheters for pressure-flow urinary study BASIC UDI-DI: 803377232CAT-U0502MJ	Class IIa
Catheters for urethral pressor without balloon BASIC UDI-DI: 803377232CAT-U0503ML	Class IIa
Catheters for measuring abdominal pressure BASIC UDI-DI: 803377232CAT-U0504MN	Class IIa
Catheters for Cavernosometry devices BASIC UDI-DI: 803377232CAT-U0505MQ	Class IIa
Urodynamic devices BASIC UDI-DI: 803377232CAT-U0580N6	Class IIa
Catheters for pelvic floor biofeedback exercise BASIC UDI-DI: 803377232CAT-U0703MW	Class IIa
Plasmafiltration devices BASIC UDI-DI: 803377232PLSL5	Class IIb
Sets for plasmafiltration BASIC UDI-DI: 803377232PLS-SETNG	Class IIb
Ultrafiltration devices for purification of dialysis fluid BASIC UDI-DI: 803377232ULT-DIANB	Class IIa
Ultrafiltration devices for purified water for reverse osmosis BASIC UDI-DI: 803377232ULT-RWOSP	Class IIa
Set of Ultrafiltration for purification of dialysis fluid	Class IIa

BASIC UDI-DI: 803377232ULT-DIA-SETPC	
Ultrafiltration devices for purified water for dental treatment units BASIC UDI-DI: 803377232ULT-AMDNE	Class IIa
Dialyzers with KUF < 18 ml/h/mmHg BASIC UDI-DI: 803377232DIA-601Y8	Class IIb
Dialyzers with KUF 18 - 35 ml/h/mmHg BASIC UDI-DI: 803377232DIA-602YA	Class IIb
Dialyzers with KUF > 35 ml/h/mmHg BASIC UDI-DI: 803377232DIA-603YC	Class IIb
Plasma fractionators BASIC UDI-DI: 803377232FRAHZ	Class IIb
Oxygenation devices for liver artery and portal vein perfusion BASIC UDI-DI: 803377232OXY-SET-HEPAZ	Class IIa
Oxygenation devices for kidney artery perfusion BASIC UDI-DI: 803377232OXY-SET-KIDB4	Class IIa
Systems for haemoperfusion and rheopheresis BASIC UDI-DI: 803377232M3A-F2K	Class IIb
Systems for hemoperfusion, therapeutic plasma exchange, rheopheresis and rheopheresis adsorption BASIC UDI-DI: 803377232M3A-M2Z	Class IIb
Systems for rheopheresis BASIC UDI-DI: 803377232M3A-T3F	Class IIb
System for hemoperfusion and endotoxins removal from blood BASIC UDI-DI: 803377232M3EGJ	Class IIb
Systems for hemoperfusion, therapeutic plasma exchange, rheopheresis and organ perfusion BASIC UDI-DI: 803377232M76-P2H	Class IIb
Systems for hemoperfusion	Class IIb

BASIC UDI-DI: 803377232M76-L29	
Systems for hemoperfusion, therapeutic plasma exchange, rheopheresis and rheopheresis adsorption BASIC UDI-DI: 803377232M76-AZG	Class IIb
Systems for organ perfusion BASIC UDI-DI: 803377232M81FT	Class IIb
BLUETOOTH TEMPERATURE SENSOR BASIC UDI-DI: 803377232M81-BTSYE	Class IIb
Measuring device for urology BASIC UDI-DI: 803377232MFZKJ	Class Im
Measuring device for urology BASIC UDI-DI: 803377232MP3J4	Class Im
Active diagnostic/rehabilitative medical devices for urodynamics BASIC UDI-DI: 803377232MPD-PSB3	Class IIa
Active diagnostic/rehabilitative medical devices for gastroenterology BASIC UDI-DI: 803377232MPD-DS9X	Class IIa
Systems for heart failure treatment BASIC UDI-DI: 803377232M48FV	Class IIb
Systems for hemoperfusion, decapneization and endotoxin removal BASIC UDI-DI: 803377232M56FU	Class IIb
Systems for haemofiltration BASIC UDI-DI: 803377232M69G5	Class IIb
Systems for haemofiltration BASIC UDI-DI: 803377232M80FR	Class IIb
Systems for oncology therapy	Class IIb

BASIC UDI-DI: 803377232MXPLL	
Warmer for haemofiltration, CRRT and hemoperfusion BASIC UDI-DI: 803377232MHTKC	Class IIb
leukocyte adsorber BASIC UDI-DI: 803377232ADSH2	Class IIa
Concentrator for plasma proteins and blood components BASIC UDI-DI: 803377232PRT-PRORP	Class IIa
Device for concentration and isolation of plasmatic proteins, exosomes, plasma vesicles, extracellular vesicles BASIC UDI-DI: 803377232PRT-EXOQJ	Class IIa

Kiwa Cermet Italia S.p.A. – Single-member company subject to management and coordination of Kiwa Italia Holding Srl
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